UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

OLENA MALICH, RACHEL CLUGSTON, ERIN SCOTT, MONICA KAPOOR, and ERIN SHEEHAN on behalf of themselves and all others similarly situated,

Plaintiffs,

V.

NUTRACEUTICAL WELLNESS, INC.,

Defendant.

Civil Action No. 1:23-cv-05652-PGG

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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I. INTRODUCTION

Defendant Nutraceutical Wellness, Inc ("Nutrafol" or "Defendant") seeks dismissal without leave to amend of Plaintiffs Olena Malich, Rachel Clugston, Erin Scott, Monica Kapoor, and Erin Sheehan's ("Plaintiffs") claims for violation of California's Consumer Legal Remedies Act, ("CLRA"), Cal. Civ. Code § 1750 *et seq.*, California's Unfair Competition Law, ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, and New Jersey's Consumer Fraud Act, ("NJCFA"), N.J. Stat. § 56:8-1, *et seq.* "to the extent [the Complaint] alleges Nutrafol falsely or deceptively advertises [its hair-growth supplements] as 'clinically proven,' 'physician formulated,' dermatologist recommended,' and comprised of 'medical-grade' ingredients." *See* Defendant Nutraceutical Wellness, Inc.'s Memorandum in Support of Motion to Dismiss the Consolidated Amended Class Action Complaint ("MTD" or "Motion") at 2, 12-17. Nutrafol's Motion should be denied in full.[1]

Ignoring Plaintiffs' cited studies that confirm that Nutrafol's "clinically proven" advertising for the Products[2] is provably false and misleading, Nutrafol seeks dismissal of Plaintiffs' California and New Jersey claims—arguing that Plaintiffs' allegations are "classic lack-of-substantiation claims." *See*, *e.g., id.* at 13. But Plaintiffs do not allege that Nutrafol's "clinically proven" representations merely lack substantiation. Instead, Plaintiffs allege that Nutrafol's

[1] Nutrafol does not argue anywhere in its MTD that Plaintiffs' claims for violation of New York's General Business Law, ("NYGBL"), §§ 349, *et seq.* or 350, *et. seq*. should be dismissed. Nor could it. *See infra* § IV.E. Nutrafol also does not challenge Plaintiffs' implied disease claims, which serve as an independent basis for Plaintiffs' claims for violation of California, New Jersey, and New York consumer protection laws. As such, even if this Court were to grant Nutrafol's motion in full, all of Plaintiffs' state consumer protection claims would survive based on Plaintiffs' allegations that Nutrafol makes unlawful implied disease claims.

[2] "Products(s)" is defined as Defendant's Nutrafol growth products including Nutrafol Women, Nutrafol Women's Balance, Nutrafol Women's Vegan, Nutrafol Postpartum, and Nutrafol Men. *See* Plaintiffs' Consolidated Amended Class Action Complaint, ECF No. 22 ("CACAC") at ¶ 1.

"clinically proven" claims are provably false and misleading. CACAC ¶¶ 3, 26-28, 32-37. Specifically, Plaintiffs allege that the very studies that Nutrafol points to in its advertising as so-called "clinical proof," will affirmatively demonstrate that Nutrafol's "clinically proven" campaign is a fraudulent scheme to sell the Products at an exorbitant premium price by deceiving consumers into believing that these are clinically proven medical grade treatments when they are, in fact, unproven hair growth supplements. *Id.* ¶¶ 1-3, 32-37. In other words, Nutrafol's "clinically proven" claims do not merely lack substantiation—affirmative evidence, including the studies that Nutrafol cites in its advertising as its clinical proof—will demonstrate that Nutrafol's "clinically proven" representations are provably false and misleading. *Id.* ¶ 35(a)-(e). As detailed below, courts across the country, including in New York, California, and New Jersey, uphold claims where plaintiffs allege that products are falsely advertised as clinically proven. The same should be true here.

In addition to misconstruing Plaintiffs' claim that Nutrafol's "clinically proven" representation is provably false and misleading as a claim merely for lack of substantiation, Nutrafol introduces questions of fact by arguing that its studies *do* provide the advertised clinical proof. *See* MTD at 2-6, 9-11. But whether the evidence, which will include studies and expert testimony, shows that the Products are "clinically proven" as represented, is a disputed issue of fact inappropriate for decision on a motion to dismiss. In a desperate last gasp on the "clinically proven" front, Nutrafol argues that Plaintiffs' personal experiences using the Products do not salvage their claims. *See id.* at 17-18. Plaintiffs' experiences, however, provide further evidence that Nutrafol's claims of clinical proof are a false and misleading advertising ploy to sell the Products at a premium price.

Finally, contrary to Nutrafol's arguments, *see id*. at 18-19, Plaintiffs plausibly allege that Nutrafol's advertising of the Products as "medical grade," "physician formulated," and "dermatologist recommended," confuse and mislead consumers to their detriment by deceiving them into believing that the Products have a scientific and medical legitimacy that they do not, in fact, have.

II. BACKGROUND

Defendant sells the Products throughout the United States at $88 for a one-month supply, primarily through online retailers Amazon.com and Sephora.com, on its own website, and in brick-and-mortar retail stores, such as Walmart. CACAC ¶ 1.

Plaintiffs allege that through its pervasive advertising campaign, Defendant deceives customers into believing the Products are proven clinically effective, and the ingredients are medical grade treatments for hormone imbalances characteristic of common hair loss diseases. *Id*. ¶ 2. In fact, contrary to the claims made by Defendant, none of the ingredients in its "clinically proven" Products are "medical grade," and they have never been approved for the treatment of any medical condition, let alone hair loss or alopecia. *Id.* ¶ 8.

Defendant's "clinically proven" representations are false and misleading because the supposed clinical studies Defendant cites in its marketing to support these claims do not, in fact, offer any competent or reliable clinical proof to support Defendant's claims. *Id.* ¶¶ 3, 35-37.

In addition, providing an independent basis for Plaintiffs' claims for violation of California, New Jersey, and New York consumer protection laws, Defendant's pervasive advertising claims, which suggest the Products treat underlying hormone imbalances characteristic of common hair loss diseases constitute deceptive implied disease claims. Defendant's advertising rises to the level of impermissible implied disease claims because it implies that the Products treat common hair

loss diseases without the requisite approval from the Food and Drug Administration ("FDA"). Defendant's misleading implied disease claims render the Products misbranded and illegal to sell as currently marketed under the Federal Food, Drug, and Cosmetic Act ("FDCA") and parallel California, New Jersey, and New York regulatory schemes and consumer protection laws. *Id.* ¶¶ 4, 48-52.

As a result of Defendant's deceptive practices, Plaintiffs and Class Members, who purchased the Products for personal, family, or household purposes during the applicable statutory period, have suffered economic injuries. *See id.* ¶¶ 20-24. Specifically, Plaintiffs would not have purchased (or would not have paid a premium for) the Products had they known: (1) the Products were not, indeed, "clinically proven" to promote hair growth; and/or (2) Defendant's representation that the Products could cure hormone imbalances characteristic of common hair loss diseases and thus promote hair growth were misleading and unapproved implied disease claims, which render the Products misbranded and illegal to sell. *Id.* ¶¶ 75-77, 85-87, 96, 101-02, 111-13.

Plaintiffs filed this action on behalf of themselves and all consumers who purchased a Product for personal, family, or household purposes from the beginning of the applicable statutory period until the date notice is disseminated. *Id.* ¶¶ 56-58. Plaintiffs Clugston and Scott assert claims against Defendant for violation of the CLRA, and the "unlawful" prong of the UCL, on behalf of a California subclass. *Id.* ¶¶ 56, 89-103. Plaintiffs Kapoor and Sheehan assert claims against Defendant for violation of NYGBL §§ 349 and 350 on behalf of a New York subclass. *Id.* ¶¶ 57, 67-88. Plaintiff Malich asserts a claim for violation of the NJCFA, on behalf of a New Jersey subclass. *Id.* ¶¶ 58, 104-115.

III. LEGAL STANDARD

To defeat a Federal Rule of Civil Procedure ("Rule") 12(b)(6) challenge, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A court "must 'accept as true all factual statements alleged in the complaint and draw all reasonable inferences in favor of the non-moving party.'" *In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d 671, 680 (S.D.N.Y. 2012) (quoting *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 1997)). Rule 12(b)(6) imposes a "plausibility" standard, not a "probability" standard…" *Anderson News*, *L.L.C. v. Am. Media*, *Inc.*, 680 F.3d 162, 185 (2d Cir. 2012) (quoting *Twombly*, 550 U.S. at 556). Plaintiffs have stated such a plausible claim for relief.

IV. ARGUMENT

A. Plaintiffs Sufficiently Allege That the Products are Provably Ineffective—Not That Defendant's Claims are Merely Unsubstantiated

Nutrafol admits that it "advertises its Products as 'clinically proven.'" MTD at 3. The problem for Nutrafol is that the Products *have not*, in fact, been "clinically proven." Nutrafol's "clinically proven" claims are part of Nutrafol's deceitful scheme to create a false aura of scientific and pharmaceutical legitimacy to sell its hair growth supplements at a premium price. *See, e.g.*, CACAC ¶¶ 1-3. Nutrafol's fraud leads consumers to pay a premium price of $88 just a one-month supply based on consumers' false belief that the Products are clinically proven, medical grade treatments for hair loss. *See, e.g.*, *id.*

Plaintiffs allege that Nutrafol's "clinically proven" representations are provably false and misleading because the studies on Nutrafol's Products that Nutrafol cites in its advertising (and in its briefing) as the basis for its "clinically proven" claims do not, in fact, offer any competent or reliable clinical proof to support Nutrafol's "clinically proven" advertising claims. *See, e.g.*, *id.* In

that regard, even Nutrafol's own study results suggest the Products are no more effective than a placebo, and the results of other studies on key ingredients Nutrafol identifies as capable of addressing hormone imbalances, have no significant effect on hormones compared to placebo. *Id.* ¶¶ 35(a)-(e), 36-37. Thus, Nutrafol's own studies and peer-reviewed scientific publications will affirmatively show that Nutrafol's "clinically proven" representations are false and misleading. *Id.* ¶¶ 35(a)-(e). In other words, Plaintiffs intend to rely on affirmative evidence to prove that Nutrafol's "clinically proven" claim is false.[3]

A lack of substantiation claim is distinguishable from a claim that a company falsely advertises that a product is clinically proven to work. *See, e.g.*, *McCrary v. Elations Co*., *LLC*, No. EDCV 13-0242 JGB, 2013 WL 6403073, at *9 (C.D. Cal. July 12, 2013) (distinguishing allegedly false clinically proven claims from the lack of substantiation claims in *National Council Against Health Fraud*, *Inc. v. King Bio Pharmaceuticals*, *Inc.*, 107 Cal. App. 4th 1336, 1342 (2003)). With lack of substantiation, the argument is that a company lacks evidence to sell its product for its stated purpose. *See id.* While claims for lack of substantiation are permissible under New York

[3] *See, e.g.*, CACAC ¶ 35(a) (citing findings of no significance compared to control in Nutrafol's Women's Balance study and alleging that, as a result, rather than providing clinical proof, Defendant's own study suggests that its product has no effect); *id.* (alleging that Defendant's menopause study is not a randomized controlled trial (RCT) and had no objective findings; thus, it does not provide clinical proof); *id.* ¶ 35(b) (citing findings of no significance compared to control in Nutrafol's Women's study and alleging that, as a result, rather than providing clinical proof, Defendant's own study suggests that its product has no effect); *id.* ¶ 35(c) (alleging that Defendant's Women's Vegan survey is not an RCT and had no objective findings; thus, it does not provide clinical proof); *id.* ¶ 35(d) (alleging that Defendant's Nutrafol Postpartum survey is not an RCT and had no objective findings; thus, it does not provide clinical proof); *id.* ¶ 35(e) (alleging that the Nutrafol Men and Women study does not provide the advertised clinical proof because it was not an RCT and thus none of the study results were objective or scientific as the study included only subjective self-assessment, and that, fatally, it excluded participants with hair loss disorders that commonly caused hair loss); *see also id.* ¶ 37 (alleging that other clinical studies on the key ingredients that in the Products suggest that those ingredients do not perform as Defendant's claim—undermining Defendant's claims that its Products are clinically proven).

law, claims for lack of substantiation are not permissible under California or New Jersey consumer protection laws. [4]

But, here, Plaintiffs do not allege a lack of substantiation: Plaintiffs do not allege that Nutrafol's unadorned assertion that its supplement supports hair growth lacks evidence. Stated otherwise, Plaintiffs do not allege that Nutrafol's fraud is in selling a hair growth supplement without evidence. Instead, Plaintiffs allege that Nutrafol's fraud is in the sale of the Products as "clinically proven" medical grade treatments for hair loss—when the evidence Nutrafol points to as so-called clinical proof in its advertising—shows no such clinical proof. CACAC ¶¶ 34-37. Nutrafol commits fraud because it goes a step beyond merely advertising its Products as a supplement for hair growth when it falsely claims that the Products are "clinically proven" to work.

Where plaintiffs allege that "clinically proven" claims are provably false and misleading, courts uphold consumer protection claims under California, and New Jersey law—and reject arguments like Nutrafol's that the plaintiffs' claims are merely for lack of substantiation. *See, e.g.*, *McCrary*, 2013 WL 6403073, at *9 (rejecting argument that allegation that "clinically proven" representation was false was an impermissible claim for lack of substantiation); *Real v. Johnson & Johnson Consumer Cos., Inc.*, No. 2:15-cv-05025-SVW-JEM, 22016 WL 3220811, at *5 (C.D. Cal. Feb. 8, 2016) (upholding claims under California consumer protection laws where the plaintiff alleged that the products were never "clinically proven" to help babies sleep better); *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 461 (E.D.N.Y. 2013) (applying California law and finding that "plaintiffs' allegation that defendants have no credible scientific evidence backing up their

[4] Nutrafol does not argue that Plaintiffs' "clinically proven" claims under the NYGBL are impermissible lack of substantiation claims. *See infra* § IV.E. Nor could it. Claims that products lack substantiation to sell are cognizable under New York law. *See id.* (citing *MacNaughton v. Young Living Essential Oils, LLC*, 67 F.4th 89, 98 (2d. Cir. 2023)).

representations is relevant in this case because Ester–C's website expressly states that there is clinical research supporting its products"); *Lieberson v. Johnson & Johnson Consumer Cos.*, *Inc.*, 865 F. Supp. 2d 529, 539-40 (D.N.J. 2011) (product labels' claim that the products were "clinically proven" to help babies sleep better was actionable as an alleged misrepresentation under NJCFA); *see also Eckler v. Wal-Mart Stores*, *Inc.*, No. 12-CV-727-LAB, 2012 WL 5382218, at *5 n.7 (S.D. Cal. Nov. 1, 2012) (distinguishing cases where plaintiffs alleged clinically proven claims were false and misleading because "[t]o be clear, Wal–Mart makes no representation that the purported benefits of Equate have been clinically proven").[5]

McCrary is instructive. *McCrary*, 2013 WL 6403073, at *9. There, the plaintiff alleged that Elations' "clinically proven" claim was literally false because no such clinical proof existed. *Id.* As Nutrafol does here, Elations argued that the plaintiff's claim regarding lack of clinical proof

[5] Courts reach the same conclusion and uphold claims alleging that "clinically proven" advertising is false and misleading under other state consumer protection laws (including under the NYGBL, which Nutrafol does not challenge). *See, e.g.*, *FTC v. Quincy Bioscience Holding, Co.*, 753 Fed. Appx. 87, 89 (2d. Cir. 2019) ("The FTC has stated a plausible claim that Quincy's representations about Prevagen [being clinically proven] are contradicted by the results of Quincy's clinical trial and are thus materially deceptive in violation of … New York General Business Law"); *Hidalgo v. Johnson & Johnson Consumer Cos., Inc.*, 148 F. Supp. 3d 285, 297 (S.D.N.Y. 2015) (upholding GBL 340 claim where the "crux" of the claim was "that the 'clinically proven' representations were misleading because 'contrary to the[ir] clear labeling and advertising, the Bedtime Products themselves are not clinically proven'" which misled consumers into believing that the products "had been clinically proven as a sleep aid"); *Noriega v. Abbott Labs.*, No. 23 CIV. 4014 (PAE), 2024 WL 402925, at *5 (S.D.N.Y. Feb. 2, 2024) (upholding claims that "clinically proven" representations were false and misleading under the GBL); *Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283, 287, 292, 299 (S.D.N.Y. 2015) (declining to dismiss claims under California and New York consumer protection laws where plaintiffs claimed that they paid a premium for products that were advertised as "clinically proven" to reduce the severity and duration of the common cold); *Leiner v. Johnson & Johnson Consumer Cos., Inc.*, 215 F. Supp. 3d 670, 673-74 (N.D. Ill. 2016) (declining to dismiss claim under the Illinois Consumer Fraud Act where the plaintiff alleged that she purchased a product at a premium because of the defendant's "clinically proven" representations); *Rikos v. Proctor & Gamble Co.*, 782 F. Supp. 2d 522, 527 (S.D. Ohio 2011) (rejecting defendant's lack of substantiation argument in case where plaintiff alleged product was falsely labeled as clinically proven)

was incognizable as a lack of substantiation claim. *Id.* The court rejected Elations' argument finding that a plaintiff "may allege no credible scientific evidence supports Elations' representations when [d]efendant puts the clinical proof for its product at issue" and concluded that "since [d]efendant's advertising expressly states that it has clinical proof to support Elations' effectiveness, [p]laintiff plausibly alleges falsity when he contends that there is an absence of such proof." *Id*. at *9. Here, too, Nutrafol expressly states that it has clinical proof to support the Products' effectiveness, putting the clinical proof for its Products at issue, and Plaintiffs plausibly allege falsity by contending that they will show that Nutrafol's "proof" does not prove its effectiveness. *See id.*

Since Plaintiffs have adequately alleged the falsity of Nutrafol's "clinically proven" advertising, Nutrafol's Motion to Dismiss Plaintiffs' California and New Jersey consumer protection claims on the ground that they are impermissible claims for lack of substantiation should be denied.[6]

B. Whether the Evidence Shows That Nutrafol's "Clinically Proven" Claims are False and Misleading is a Disputed Issue of Fact Inappropriate for Decision on a Motion to Dismiss

Once the Court dispenses with Nutrafol's attempt to confuse Plaintiffs' well-pled claim that Nutrafol's "clinically proven" claims are provably false and misleading with a claim for a lack of substantiation, the only arguments that remain in Nutrafol's Motion to Dismiss are factual arguments that the studies provide clinical proof. These arguments do not support Nutrafol's bid for dismissal because whether the evidence shows that Nutrafol's "clinically proven" claims are false and misleading is a disputed issue of fact that is inappropriate for a decision on a motion to

[6] Again, Nutrafol can make no lack of substantiation argument under New York consumer protection law because plaintiffs may allege a lack of substantiation in New York. *See infra,* § IV.E.

dismiss. *See, e.g.*, *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 543-44 (S.D.N.Y. 2013) ("Whether or not the studies support plaintiff's proposition that it is 'biologically impossible' to rebuild cartilage is an issue of fact the [c]ourt cannot resolve on a motion to dismiss."); *Daynan v. Swiss-Am. Prods.*, *Inc.*, No. 15 Civ. 6895 (DIL), 2017 WL 9485702, at *13 (E.D.N.Y. Jan. 3, 2017); *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 140 (E.D.N.Y. 2015) (agreeing that "issues of fact, credibility, and the weight of the evidence are not properly considered on a motion to dismiss"); *Noriega*, 2024 WL 402925, at *5 (denying the motion to dismiss on the basis that "at the motion-to-dismiss phase, it is not the [c]ourt's province to look beneath a facially colorable methodological critique where doing so would require resolving factual disputes and/or making scientific assessments.").

In addition, while it would be inappropriate to convert this Motion into a motion for summary judgment, whether or not Nutrafol's "clinically proven" claims are false and misleading will be a disputed issue of fact at the summary judgment stage. *See, e.g.*, *In re Gerber Probiotics Sales Pracs. Litig.*, No. 12-835 (JLL), 2013 WL 4517994, at *8 (D.N.J. Aug. 23, 2013) (holding that "it is not appropriate to consider the content of the studies and resolve the factual issues at this stage of the litigation" and denying motion to dismiss where the parties disagreed as to the findings of certain studies); *Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 876 (N.D. Cal. 2016) (denying summary judgment "[i]n light of the myriad triable issues of fact" where both parties offered expert testimony and scientific literature in support of their positions).

In that regard, while Nutrafol claims that the advertised studies performed on the Products support Nutrafol's "clinically proven" claims, Plaintiffs allege just the opposite. As the below chart shows, the Parties dispute whether the studies that Nutrafol relies upon as clinical proof in its

advertising campaign—and in its briefing—offer the clinical proof that Nutrafol ubiquitously advertises:

Studies relied on by Nutrafol in its advertising in support of its advertised claims of "clinical proof"	**Nutrafol's claims about its studies in its Motion to Dismiss:**	**Plaintiffs' allegations showing that the studies do not provide the advertised clinical proof**
Ablon et al., *A Six-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Women With Self-Perceived Thinning Hair*, 17 J. Drugs Dermatology 558 (2018)	MTD at 3: This randomized, double-blind, placebo-controlled study followed women aged 21 to 65 using Nutrafol Women over six months. *See* Ablon 2018 at 558-59. It concluded Nutrafol Women "significantly increase[d] the number of terminal and vellus hairs based on macrophotography analysis, and significantly increase[d] hair growth and hair quality based on Blinded Investigator Global Hair Assessments." *Id*. at 564.	Citing findings of no significance compared to control in Nutrafol's Women's study and alleging that, as a result, rather than providing clinical proof, Defendant's own study suggests that its product has no effect. CACAC ¶¶ 35(b), 36, n.23.
Ablon et al., *A Randomized, Double-Blind, Placebo-Controlled Study of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal, and Postmenopausal Women With Thinning Hair*, 20 J. Drugs Dermatology 55 (2021)	MTD at 3: This randomized, double-blind, placebo-controlled study followed perimenopausal, menopausal, and postmenopausal women using Nutrafol Women's Balance over the course of six months. *See* Ablon 2021 at 56. It concluded Nutrafol Women's Balance could "safely and effectively improve hair growth and quality in perimenopausal, menopausal, and postmenopausal women with thinning hair." *Id*. at 61. Specifically, "[t]he number of total, terminal, and vellus hair counts, and hair shedding all significantly improved compared to placebo." *Id*.	Citing findings of no significance compared to control in Nutrafol's Women's Balance study and alleging that, as a result, rather than providing clinical proof, Defendant's own study suggests that its product has no effect. CACAC ¶¶ 35(a), 36, n.23.

Ablon et al., *A Long-Term Study of the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal, and Postmenopausal Women*, 21 J. Drugs Dermatology 776 (2022)	MTD at 4: This study was a continuation of the previous one regarding perimenopausal, menopausal, and postmenopausal women using Nutrafol Women's Balance. *See* Ablon 2022 at 778. "[P]reviously placebo-treated subjects were switched to treatment with the active supplement," and "[t]he investigator and both subject groups all remained blind to the original treatment received during Phase I[.]" *Id*. at 777. The study concluded that "[c]ontinuous use [of Nutrafol Women's Balance] may provide ongoing improvements in hair growth and exert a positive effect on secondary symptoms of menopause, as well as quality of life." *Id*. at 783.	Citing findings of no significance compared to control in Nutrafol's Women's Balance study and alleging that, as a result, rather than providing clinical proof, Defendant's own study suggests that its product has no effect. CACAC ¶¶ 35(a), 36, n.23.
Stephens et al., *A Prospective Six-Month Single-Blind Study Evaluating Changes in Hair Growth and Quality Using a Nutraceutical Supplement in Men and Women of Diverse Ethnicities*, 15 J. Clinical & Aesthetic Dermatology 21 (2022)	MTD at 5: This single-blind study followed men aged 20 to 55 and women aged 20 to 45 using Nutrafol Men and Nutrafol Women, respectively, over the course of six months. *See* Stephens 2022 at 3. Participants included African American, Asian, and Hispanic individuals. *See id*. at 4. The study concluded that "daily administration of a standardized nutraceutical is effective in improving visible hair growth, volume/thickness/fullness, and coverage with less noticeable hair shedding for men and women of various ethnic backgrounds." *Id*. at 8. It also noted "[m]any self-assessment parameters continued to improve at Week 24 suggesting additional improvement may occur with continued product use." *Id*.	Alleging that the Nutrafol Men and Women study does not provide the advertised clinical proof because it was not a double-blind placebo randomized controlled trial and thus none of the study results were objective or scientific as the study included only subjective self-assessment, and that, fatally, it excluded participants with hair loss disorders that commonly caused hair loss. CACAC ¶ 35(e).

Berkowitz et al., *Evaluating the Efficacy of a Standardized Nutraceutical to Improve Hair Growth and Quality in Menopausal Women: A Nine Month Subjective Single-Blind Prospective Study*, American Society for Dermatologic Surgery Virtual Annual Meeting (2020)	MTD at 5-6: This single-blind study followed pre-, peri- and post-menopausal women with self-perceived thinning hair taking Nutrafol's Synergen Complex Plus for nine months. *See* Berkowitz 2020. "Both subjects and expert graders reported hair growth and quality and saw further improvements throughout the duration of the study in addition to overall well-being parameters." *Id*.	Alleging that Defendant's menopause study is not a randomized controlled trial (RCT) and had no objective findings; thus, it does not provide clinical proof. CACAC ¶ 35(a).

As such, based on the very Product studies that Nutrafol points to as clinical proof, Plaintiffs sufficiently allege that Nutrafol's "clinically proven" advertising is false and misleading. This is sufficient at the pleading stage. *See, e.g.*, *Vasic v. Patent Health*, *LLC*, No. 13cv849 AJB, 2014 WL 940323, at *4 (S.D. Cal. Mar. 10, 2014) (holding that the plaintiff's claims were facially plausible because of the scientific studies cited in support and finding that "the issue of whether the proffered studies to in fact show that [d]efendant's representations are provably false is a question not properly decided on a motion to dismiss").

Additionally, providing further support for the proposition that Nutrafol's "clinically proven" representations are false, Plaintiffs cite additional studies to demonstrate that the key ingredients highlighted in Nutrafol's advertising of the Products do not function as Nutrafol represents. CACAC ¶ 37. For example, in its advertising, Nutrafol points to "saw palmetto" as a key ingredient and claims that it impacts DHT hormone to promote hair growth. *Id*. ¶¶ 7, 50(a), 50(b), 50€. Contrary to this claim, Plaintiffs allege that the only human study to examine the effect

of "saw palmetto" on DHT observed no effect. *Id*. n.24.[7] Accordingly, while this study addresses only one of the key ingredients that Nutrafol touts, the fact that its findings are contrary to Nutrafol's advertising about that particular ingredient provides further evidence to the mountain of proof showing that the Products are not "clinically proven" as Nutrafol deceptively represents.

In another example, in its advertising, Nutrafol points to "ashwagandha" as a key ingredient for balancing stress hormones to promote hair growth. *Id*. ¶¶ 7, 50(a), 50(b), 50(c), 50(e). Contrary to this claim, Plaintiffs allege that at least one study has found, when compared to a placebo, "ashwagandha" had no effect on stress hormones. *Id*. n.25.[8] The fact that a placebo-controlled trial found that the "ashwagandha" ingredient, which Nutrafol touts as balancing stress hormones, is no different from a placebo provides yet more evidence for Plaintiffs' allegation that Nutrafol's claims of clinical proof are fraudulent.

Furthermore, again underlining that Nutrafol's claims of clinical proof and medical grade efficacy are fraudulent, Plaintiffs allege that other ingredients in the Products, including selenium, biotin, and vitamin A (such as beta-carotene), would only impact hair growth in rare cases of extreme dietary deficiency. *Id*. n.26.[9]

In an attempt to distract from these well-pled allegations in Plaintiffs' CACAC, Nutrafol spends several pages of its brief arguing that the single-ingredient studies cited by Plaintiffs regarding "saw palmetto" and "ashwagandha" do not prove that the multi-ingredient Products at

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[7] Citing R. Llewellyn-Huntley, *The Truth About Saw Palmetto for Hair Loss* (Jan. 21, 2022) https://menscript.com/uk/articles/saw-palmetto-for-hair-loss-popular-but-ineffective (last visited Aug. 28, 2023).

[8] Citing Lorpresti, Adrian L. et al, *A Randomized, Double-Blind, Placebo-Controlled, Crossover Study Examining the Hormonal and Vitality Effects of Ashwagandha (Withania somnifera) in Aging, Overweight Males*, AM J MENS HEALTH. 2019 Mar-Apr; 13(2): 1557988319835985 (last accessed Aug. 28, 2023).

[9] Citing Nutrafol Review: Half-Truths, Cherrypicked Data, & Misleading Study Results, https://perfecthairhealth.com/nutrafol-review/ (last visited Aug. 28, 2023).

issue do not work. MTD at 15-16. Nutrafol's argument fails because it ignores: (1) the gravamen of Plaintiffs' claim is that that Nutrafol's "clinically proven" advertising campaign is fraudulent; not that Nutrafol lacks substantiation to sell a hair growth supplement; and (2) Plaintiffs' claims rest on *Nutrafol's own Product studies* and not just the single-ingredient studies that further underline the fact that the clinical proof that Nutrafol advertises does not really exist. Plaintiffs' citation to studies that suggest that the ingredients that Nutrafol touts as having particular effects do not, in fact, have such effects compared to placebo, provide additional support for Plaintiffs' argument that the Products are not "clinically proven" as Nutrafol advertises.

None of the cases relied upon by Nutrafol support dismissal of Plaintiffs' claims based on the falsity of Nutrafol's "clinically proven" advertising. Nutrafol's citation to *Scheuerman v. Nestle Healthcare Nutrition*, *Inc*., No. 10-3684 (FSH), 2012 WL 2916827 (D.N.J. July 17, 2012) is unhelpful. *See* MTD at 17. First, *Scheuerman* is a summary judgment decision that is not applicable at the motion to dismiss stage. Second, *Scheuerman* is distinguishable. In *Scheuerman*, after the submission of evidence and expert testimony, the plaintiff failed to prove that the defendant's clinically proven claims were false because the plaintiff's own experts admitted that there was some limited clinical proof for the advertising claims at issue. *Id*. at *8. Here, on the other hand, as detailed above, Plaintiffs plausibly allege the falsity of Nutrafol's "clinically proven" claims based on Nutrafol's own studies and other scientific evidence.

Engel v. Novex Biotech, *LLC*, 689 Fed. App'x 510 (9th Cir. Apr. 21, 2017) and *Corbett v. Pharmacare U.S.*, *Inc*., 544 F. Supp. 3d 996 (S.D. Cal. 2021), do not help Nutrafol either. *See* MTD at 16-18. In those cases, the plaintiffs failed to point to affirmative evidence showing the falsity of "clinically tested" representation by only alleging that a comprehensive search could not produce any published clinical testing. Similarly, in *Perez v. Bath & Body Works*, *LLC*, the plaintiff

merely alleged that "[h]ad [d]efendants actually done any 'clinical testing,' they would have known all their representations are totally bogus," which failed to plausibly allege the falsity of the clinically tested claims. No. 21-cv-05606-BLF, 2022 WL 2756670, at *4 (N.D. Cal. Jul. 14, 2022).

Here, Plaintiffs go much further in alleging falsity than the plaintiffs in *Engel*, *Corbett*, and *Perez*. Indeed, here, for example, Plaintiffs point to findings in the very studies that Nutrafol cites in its advertising as supposed "clinical proof" that actually suggest that the Products themselves have no effect, CACAC. ¶¶ 3, 35-37, as well as other studies that suggest that the key ingredients that Nutrafol focuses its advertising do not have the effects that Nutrafol claims as affirmative evidence showing the falsity of Nutrafol's ubiquitous "clinically proven" advertising. *Id*. ¶¶ 35(a)-(e), 36-37. Plaintiffs also cite a letter to the Federal Trade Commission ("FTC") prepared by TruthinAdvertising.org, which carefully outlines the methodological deficiencies in Nutrafol's studies. *Id.*, Ex. 6. As such, the CACAC sets forth, with a great degree of specificity, the precise shortcomings of Nutrafol's studies (both with respect to the fully constituted Products and the constituent ingredients) and explains why those documented shortcomings render Nutrafol's "clinically proven" claims materially false and misleading with respect to each of the five Nutrafol Products at issue. *See id.* ¶ 35(a)-(e).

In sum, while Nutrafol goes to great lengths to mischaracterize Plaintiffs' claims, Plaintiffs do not merely claim that Nutrafol failed to support its advertising with reliable evidence. Instead, relying on peer-reviewed scientific publications and Nutrafol's own studies, Plaintiffs sufficiently allege that Nutrafol's advertising claims that the Products are "clinically proven" to work are provably false and misleading in violation of California, New Jersey, and New York consumer protection laws.

C. Allegations of Plaintiffs' Anecdotal Experiences are Not Necessary Where Allegations are Supported by Scientific Studies

In a strained attempt to move the goalposts and muddy the waters, Nutrafol argues in the alternative, that Plaintiffs' allegations concerning their personal experiences using the Products are not sufficient to plausibly allege that Nutrafol's "clinically proven" advertising claims are false. MTD 17-18. Nutrafol argues that Plaintiffs fail to allege proper usage of the Products, and, in any event, their subjective experiences are irrelevant in assessing clinical efficacy. *Id*.

As demonstrated above, Plaintiffs have more than sufficiently alleged that Nutrafol's "clinically proven" claims are demonstrably false, both with reference to Nutrafol's methodologically flawed studies, as well independent studies of the key ingredients used in Nutrafol Products. Nutrafol's reliance upon *Tubbs v. AdvoCare International*, *LP* is unavailing since that holding was limited to dismissing false advertising claims predicated exclusively upon anecdotal evidence and without any relevant scientific evidence having been offered in support. 785 F. App'x 396 (9th Cir. 2019). Likewise, *Martin v. Onnit Labs Inc*. involved the dismissal of a false advertising claim bolstered by nothing other than the alleged personal experiences of the plaintiff, rather than supporting studies. No. 2:23-cv-03737-FWS, 2023 WL 8190712 (C.D. Cal. Oct. 18, 2023).

On the contrary, whereas here, claims alleging deceptive advertising are supported by anecdotal evidence ***and*** scientific studies, dismissal is unwarranted. *See Mosher-Clark v. Gravity Defyer Med. Tech. Corp*., No. 22-cv-05288-HSG, 2023 WL 5836976, at *4 (N.D. Cal. Sep. 8, 2023) (holding that "allegation[s] … supported by anecdotal evidence, including [plaintiff's] personal experience, twenty-one other customer complaints, and the UCLA Study and subsequent FTC suit … are sufficient to survive a motion to dismiss.").

Having plainly set forth the scientific basis for their claims that Nutrafol's "clinically proven" claims are baseless, Plaintiffs had no need to "salvage" their claims by relying upon allegations recounting their personal experiences. *Mosher-Clark*, 2023 WL 5836976, at *4. As such, Nutrafol's argument for dismissal on this specious basis should be denied.

D. Plaintiffs Sufficiently Allege That Defendant's Advertising Claims That the Products are "Physician Formulated," "Dermatologist Recommended," and "Medical Grade" are Deceptive

Contrary to Nutrafol's arguments, Plaintiffs plausibly allege that Nutrafol's advertising of Products as "medical grade," "physician formulated" and "dermatologist recommended" is deceptive because those advertising claims bestow the Products with a false scientific legitimacy that the Products do not actually have.

First, Nutrafol's advertising of the Products as "medical grade" is false. There are only three "medical grade" drugs on the market capable of medically treating hair loss—minoxidil, finasteride, and baricitinib. *See* CACAC ¶ 8. Nutrafol's Products contain none of these drugs and, as discussed herein at length, are not clinically proven to promote hair growth. *See, e.g.*, *MacNaughton*, 67 F.4th at 97 (relying on the Oxford English Dictionary, the Second Circuit held that "therapeutic-grade" has an objective meaning that is likely to mislead consumers into believing that a product is "an effective treatment" for various medical conditions).

To the extent that Nutrafol argues that Plaintiffs fail to allege the Products are not "physician formulated" or "dermatologist recommended," and therefore fail to allege falsity, Nutrafol misapprehends and misrepresents Plaintiffs' claims. Nutrafol's representations about physician formulation and physician recommendation, even if technically true, are still misleading and are part of Nutrafol's overall fraud to create a false sense of medical legitimacy to sell the Products at a premium price. Advertising may be misleading, but not false, if it has a "'likelihood or tendency to deceive or confuse the public.'" *People ex rel. Dept. of Motor Vehicles v. Cars 4*

Causes, 43 Cal. Rptr. 3d 513, 521 (Cal. Ct. App. 2006) (quoting *Kasky v. Nike Inc.*, 45 P.3d 243, 250 (Cal. 2002)); *see also Capaci v. Sports Research Corp.*, 445 F. Supp. 3d 607, 620 (C.D. Cal. 2020) (noting that California consumer statutes "prohibit (1) false advertising and (2) advertising that is literally true, but which is 'actually misleading or which has a capacity, likelihood, or tendency to deceive or confuse the public.'") (quoting *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 846 (9th Cir. 2019)); *Tiffany (NJ) Inc. v. Ebay Inc.*, 600 F.3d 93, 112 (2d Cir. 2010) ("A claim of false advertising may be based on at least one of two theories: 'that the challenged advertisement is literally false, *i.e.*, false on its face,' or 'that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers.'") (quoting *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 153 (2d Cir. 2007)); *Eberhart v. LG Elecs. USA, Inc.*, No. 15-1761, 2015 WL 9581752, at *4 (D.N.J. Dec. 30, 2015) ("A statement need not be literally false in order to constitute an actionable representation under the CFA because 'in an action under the CFA, the test is whether an advertisement has the capacity to mislead the average consumer. Even if an advertisement is literally true, it may be actionable if the overall impression [it] create[s] . . . is misleading and deceptive to an ordinary reader.'") (quoting *Union Ink Co. v. AT&T Corp.*, 352 A.2d 361, 644 (N.J. Super. Ct. App. Div. 2002)). Here, Plaintiffs have sufficiently alleged injury and that Nutrafol's conduct of selling the Products as physician formulated or dermatologist recommended treatments is misleading given that it, in fact, has no clinical proof to support its "clinically proven" claims.[10]

[10] Plaintiffs' allegations that Nutrafol's "physician formulated" and "dermatologist recommended" statements are deceptive also support Plaintiffs' separate claims that Nutrafol makes misleading implied disease claims without regulatory approval in violation of California, New Jersey, and New York consumer protection laws. *See Corbett v. Pharmacare U.S., Inc.*, 567 F. Supp. 3d 1172, 1181, 1192-93 (S.D. Cal. 2021) (holding that claims that an elderberry extract was "virologist-developed" for immune support necessarily imply disease prevention or treatment); *see also infra* § IV.F.

Consequently, Nutrafol's advertising claims that the Products are "medical grade," "physician formulated," and "dermatologist recommended" are actionable misrepresentations.

E. Plaintiffs' NYGBL Claims, Which Nutrafol Fails to Challenge, Should be Upheld

Nutrafol does not discuss New York law in its Motion and does not argue that Plaintiffs Sheehan or Kapoor (the "New York Plaintiffs") have failed to plead NYGBL claims. Nutrafol has thus failed to move to dismiss the New York Plaintiffs' NYGBL claims, and those claims can thus be upheld without any decision or analysis by the Court.

While Nutrafol's lack of substantiation argument misconstrues Plaintiffs' allegations and is unpersuasive under California and New Jersey consumer protection laws, the lack of substantiation doctrine does not even exist under New York law. Defendant, thus, can make no argument under NYGBL §§ 349 and 350 about lack of substantiation. *MacNaughton*, 67 F.4th at 98 (rejecting the "argument that the New York General Business Law does not protect against advertising that lacks substantiation" as unpersuasive and not supported by any New York case law).

Indeed, the New York Plaintiffs have sufficiently alleged both NYGBL claims, and any argument to the contrary raised by Nutrafol on reply should be rejected as waived. The CACAC amply sets forth allegations that Nutrafol's Product advertising was directed at consumers, CACAC ¶¶ 4, 10-11, 13-14, 34, that the "clinically proven" claim is materially false and misleading because the studies in support of such a claim actually provide no clinical proof, *id.* ¶¶ 32-37, and that the New York Plaintiffs have been injured as a result of being induced to purchase

Nutrafol's Products when they either would not have purchased them (if they were not misled) or, alternatively, would not have paid the price premium demanded by Nutrafol. *Id.* ¶¶ 23-24. [11]

Additionally, as mentioned herein, courts uphold claims alleging that "clinically proven" representations are false and misleading under the NYGBL. *See*, *Quincy Bioscience Holding, Co.*, 753 Fed. Appx. at 89; *Hidalgo*, 148 F. Supp. 3d at 297; *Noriega*, 2024 WL 402925, at *5.

The recent decision in this district in *Noriega* is on point. 2024 WL 402925. In *Noriega*, the putative class action plaintiff asserted NYGBL §§ 349-350 claims in connection with Abbott's deceptive marketing of its Pediasure Grow and Gain Drink product, which was falsely marketed as having been "[c]linically proven to help kids grow." *Id.* at *1-2. Abbott moved to dismiss under Rule 12(b)(6), arguing, as Nutrafol does here, that "the clinical studies cited on its website support that Pediasure has been clinically proven to help kids grow, and therefore it is implausible to term that [it's clinically proven claims are] materially misleading." *Id.* at *4. However, relying upon the robust methodological critiques of the Abbott funded studies referenced in the complaint, along with other published literature disputing their clinical significance, the court in *Noriega* denied the motion to dismiss on the basis that "at the motion-to-dismiss phase, it is not the [c]ourt's province to look beneath a facially colorable methodological critique where doing so would require resolving factual disputes and/or making scientific assessments." *Id.* at *5.

[11] NYGBL § 349 prohibits deceptive acts and practices "that are likely to mislead a reasonable consumer acting reasonably under the circumstances" and provides a cause of action for persons injured by such an act. *Himmelstein, McConnell, Gribben, Donoghue & Joseph, LLP v. Matthew Bender & Co., Inc.*, 37 N.Y.3d 169, 178 (2021); *Chen v. Dunkin' Brands, Inc.*, 954 F.3d 492, 500 (2d Cir. 2020). NYGBL §§ 349 and 350 claims only need to be pled to satisfy the notice pleading requirements of Fed. R. Civ. P. 8. *See Hidalgo*, 148 F. Supp. 3d at 294. Such claims do not have to be pled with particularity under Fed. R. Civ. P. 9(b). *Id.*; *Velez v. Lasko Prods., LLC*, No. 1:22-cv-08581 (JLR), 2023 WL 8649894, at *2 (S.D.N.Y. Dec. 14, 2023). Further, a whether a reasonable consumer would be misled "is generally a question of fact not suited for resolution at the motion to dismiss stage. *See Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 95 (S.D.N.Y. 2021).

While Nutrafol does not specifically address the NYGBL claims in the CACAC, it does engage in a premature and procedurally misplaced factual debate concerning the relative merits (or, more precisely, the lack thereof) of its own studies, all of which, as discussed herein, are thoroughly dissected, and refuted in the CACAC as being hopelessly manipulated, thoroughly unrepresentative, and scientifically irrelevant. CACAC ¶¶ 34-37; *Noriega*, 2024 WL 402925, at *5; *supra* §§ IV.A-B.

As such, to the extent Nutrafol's Motion to Dismiss challenges the sufficiency of the New York Plaintiffs' NYGBL §§ 349-350 claims (which it does not appear to do), Nutrafol's Motion must be denied.

F. Nutrafol Fails to Challenge Plaintiffs' Implied Disease Claims and Has Thus Waived Any Argument for Dismissal

Importantly, Plaintiffs also allege that Nutrafol uses implied disease claims in its advertising, which have not been approved by the FDA, and thus renders the Products misleadingly misbranded and illegal to sell under the FDCA, parallel state laws incorporating the FDCA by reference, and state consumer protection law. CACAC ¶¶ 4, 38-54. Plaintiffs allege Nutrafol's use of implied disease claims serves as an independent basis for Plaintiffs' claims for violation of California, New Jersey, and New York consumer protection laws. *See id.* By failing to challenge Plaintiffs' allegations that Nutrafol makes implied disease claims in violation of consumer protection law, Nutrafol has waived its ability to move to dismiss those claims. As such, even if this Court were to grant Nutrafol's Motion in full, all of Plaintiffs' state consumer protection claims would survive based on Plaintiffs' allegations that Nutrafol makes unlawful implied disease claims.[12]

[12] *See Am. Infertility of N.Y., P.C. v. CNY Fertility, PLLC*, No. 21-CV-5566 (JMF), 2021 WL 4803539, at *1 (S.D.N.Y. Oct. 13, 2021) (denying motion to dismiss to the extent it was based on an argument that the defendant failed to address until its reply brief); *Ct. Bar Ass'n v. United States*,

V. CONCLUSION

For the reasons set forth herein, Defendant's Motion should be denied in its entirety.

620 F.3d 81, 91 n.13 (2d Cir. 2010) ("Issues raised for the first time in a reply brief are generally deemed waived."); *Mayer v. Neurological Surgery, P.C.*, No. 15-CV-0864(DRH), 2016 WL 347329, at *4 (E.D.N.Y. Jan. 28, 2016) ("The law in this [c]ircuit is clear that arguments raised for the first time in reply briefs need not be considered."); *Cotona v. Fed. Bureau of Prisons*, No. 13 Civ. 609(JMF), 2013 WL 5526238, at *2 (S.D.N.Y. Oct. 7, 2013) ("arguments raised for the first time in a reply memorandum are waived and need not be considered").

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James R. Denlea
Jeffrey I. Carton
Stan Sharovskiy
DENLEA & CARTON LLP
2 Westchester Park Drive, Suite 410
White Plains, New York 10604
Tel.: (914) 331-0100
Fax: (914) 331-0105
jdenlea@denleacarton.com
jcarton@denleacarton.com
ssharovskiy@denleacarton.com

Annick M. Persinger*
TYCKO & ZAVAREEI LLP
1970 Broadway, Suite 1070
Oakland, CA 94612
Tel: (510) 254-6808
Fax: (202) 973-0950
apersinger@tzlegal.com

Allison W. Parr
TYCKO & ZAVAREEI LLP
2000 Pennsylvania Avenue, Northwest, Suite 1010
Washington, District of Columbia 20006
Tel: (202) 973-0900
Fax: (202) 973-0950
aparr@tzlegal.com

Melissa S. Weiner
Ryan T. Gott*
PEARSON WARSHAW, LLP
328 Barry Ave. S., Suite 200
Wayzata, MN 55391
Tel: (612) 389-0600
Fax: (612) 389-0610
mweiner@pwfirm.com
rgott@pwfirm.com

Jeff Ostrow
Kristen Lake Cardoso*
KOPELOWITZ OSTROW P.A.
One West Las Olas Blvd., Suite 500

Fort Lauderdale, Florida 33301
Tel: (954) 525-4100
Fax: (954) 525-4300
ostrow@kolawyers.com
cardoso@kolawyers.com

Rachel L. Soffin
MILBERG COLEMAN BRYSON PHILLIPS GROSSMAN, PLLC
800 S. Gay Street, Suite 1100
Knoxville, TN 37929
Tel: (865) 247-0080
Fax: (865) 522-0049
rsoffin@milberg.com

Nick Suciu III*
MILBERG COLEMAN BRYSON PHILLIPS GROSSMAN, PLLC
6905 Telegraph Rd., Suite 115
Bloomfield Hills, MI 48301
Tel. (313) 303-3472
nsuciu@milberg.com

Philip M. Smith
KRAVIT SMITH LLP
75 South Broadway, Suite 400
White Plains, New York 10601
Tel.: (646) 433-8004
Fax: (917) 858-7101
psmith@kravitsmithllp.com

**admitted pro hac vice*

Attorneys for Plaintiffs and the Proposed Class